February 14, 2005

HAND-DELIVERED

Jonathan Trout, Secretary /Treasurer
Louisville Metro Air Pollution Control District
850 Barret Avenue
Louisville, Kentucky 40204-1745

RE: Air Toxics Regulations - STAR Program
Formal Comments
E. I. du Pont de Nemours and Company, Louisville Works

Dear Mr. Trout:

DuPont thanks the Air Pollution Control District (District) for the opportunity to comment on the proposed air toxics regulations, hereafter referred to as the STAR program. DuPont is committed to safe and environmentally responsible operations in Louisville and in all areas where we operate. We welcome any opportunity to work with the District towards the goal of ensuring a healthful environment in Jefferson County.

DuPont supports the District's goal of ensuring clean air for all citizens of the County. However, we have major concerns regarding the implementation process and content of the proposed STAR regulatory package as outlined in the attached comments.

DuPont participated in development of the regulations from the Louisville Chemistry Partnership (LCP) and supports the comments made by that group. Further, DuPont supports, in large, the comments submitted by Greater Louisville Inc., and the Associated Industries of Kentucky (AIK).

DuPont submits these comments to the District in good faith and trusts that the District will give thorough consideration and response to each concern. DuPont requests that the District allow further formal input and comment by engaging stakeholder input and opening the rule-making process to further formal comment. Please direct any questions regarding these comments to me at (502) 775-3173 or Cheryl.S.Fisher@usa.dupont.com.

Respectfully submitted,

Cheryl S. Fisher
Area Manager - Environmental

cc: Jonathan Trout, LMAPCD Secretary/Treasurer
The Honorable Jerry Abramson, Louisville Metro Mayor
Mr. Bruce Traughber, Cabinet Secretary
Dr. Karen A. Cassidy, APCD Board Chair
Mr. Lewis H. Hammond, APCD Board Member
Mr. Lee Howard, APCD Board Member
Ms. Barbara Sexton Smith, APCD Board Member
Ms. Sandra Withers, APCD Board Member
Dr. Nadir Al-Shami, MD, APCD Board Member
Ms. Carolyn Embry, APCD Board Member

EXECUTIVE SUMMARY

At a special Committee of the Whole called on January 13, 2005, the Board (APCD Board) voted to formally propose the regulations by making public notice on January 14. Since the preliminary regulatory impact analysis and the response to informal comments (more than 200 pages) were released only on January 12, 2005, it appears that the Board moved to action without careful consideration of these important documents.

The Board moved to a 30-day public comment period, which has proved insufficient for comprehensively assessing the broad impact of these new and revised regulations. Therefore, the Louisville Chemistry Partnership, of which DuPont is a member, requested a 30-60 day extension of the formal comment period.

The complexity of the proposed air toxics program warrants careful consideration of the impact of steps taken towards addressing all significant sources for meeting the intended goal. The hurried manner in which the District has pursued these regulations does not lend itself to such a process. Design of any program should be input-based and have a clear understanding of the impacts of the program toward the goal. DuPont recommends that the District take the necessary time and energy to engage a true stakeholder process to develop regulations that serve the stated objectives without imposing unproductive requirements. While DuPont appreciates the public informational meetings offered by the District over the past few months, there was not true stakeholder engagement during that process.

IMPACT TO REGULATED BUSINESSES

The STAR program, as proposed, has the potential to cause an unfavorable business environment for existing or new companies in Jefferson County.

There should be a clear, transparent plan for funding the extensive STAR regulations. Thus far, the District has not disclosed a plan for funding the STAR program beyond FY2005. During informal public meetings, the District stated that funding for the STAR program for FY2005 would come from three sources - $261,000 from permit fees, $260,000 from an EPA grant, and $174,000 from the VET surplus. The plan for making up the difference left when the EPA grant and VET surplus are no longer available has not been disclosed. The APCD should divulge plans for funding the STAR program beyond FY2005. If no plan exists, the District should develop a plan, which should be disclosed and subject to further public review and comment, prior to implementation of the STAR program elements. See further comments for Regulation 2.08 below.

The risk assessment methods used in the regulations, which incorporate many layers of conservatism, are flawed, as outlined in the following comments. DuPont agrees with the District that it is necessary and prudent to protect public health, but disagrees with the methods by which the District has proposed to accomplish this goal.

Further, the subjectivity built into the regulations (for example, modified environmental acceptability procedure) could lead to unfair implementation amongst the various

companies in the County, resulting in an uncertain business climate and competitive disadvantage. These factors are important when a company, including DuPont, decides where and when to expand operations and create jobs.

DuPont believes the STAR program to be over-reaching for industrial applicability, while not addressing other, more significant sources of toxic air contaminants. In the regulatory impact analysis, the District attempted to estimate impact on businesses subject to the regulation. However, DuPont believes those estimates to be understated, particularly in respect to the costs for a separate leak detection and repair program and the expense involved in modeling TACs.

SCOPE OF REGULATIONS

DuPont believes that the District has not carefully considered the regulations with regard to desired outcomes. Without following an input-based decision making process, the District essentially does not solve the existing issues with chemicals that may be above acceptable risk levels. While DuPont supports the goal of the District to do "no further harm," the methodology and implementation plan is not appropriate and likely leads to substantial, undue burden on Title V stationary sources, while not adequately addressing current suspected risk.

The STAR program focuses only on a small segment of the air toxic sources. In response to comments made during the informal comment period, the District has added Regulation 5.30. DuPont believes this approach to be inadequate for comprehensively addressing the air issues in the County. Essentially, the STAR program shoulders the burden of improved air quality on Title V and FEDOOP companies by imposing standards and goals that are, in some cases, technically unachievable, while not simultaneously seeking improvement from other, more significant, sources.

THE METHOD

DuPont has concerns about the methodology for determination of environmental acceptability as described in the proposed regulations. Specifically, the method is extremely conservative and is presented in a manner that, in some cases, lacks clarity, rendering it difficult for the reader to follow and interpret impacts on their facility. Detailed concerns regarding methodology for determining risk are presented in the comments that follow.

LAYERS OF CONSERVATISM

The methodology described for assessing the environmental acceptability for toxic contaminants contains too many layers of conservatism for the assessment results to be practical. Examples of conservatism in the assessment process are:

- Choosing to use a risk level of one-in-a-million as a bright line of acceptable risk for carcinogens, and choosing a hazard index of 0.2 for non-carcinogens. Establishing acceptable risk standards at a de minimus level of one-in-a million is a policy decision that bears revisiting. EPA uses a risk range of $1x10^{-4}$ to $1x10^{-6}$

in its Benzene NESHAP program, for example, and considers other important factors such as population risk and economic factors to arrive at a level that provides an ample margin of safety for resident while not overburdening industry.

- Multiple uncertainty factors are included in available inhalation health benchmarks that can easily be on the order of 1000 times more stringent to account for uncertainty.

- If inhalation health benchmarks are derived from oral values, additional uncertainty enters the assessment to account for the extrapolation from the oral route to the inhalation route.

- Targeting maximum daily ambient air concentrations and assuming they apply over a lifetime of exposure in lieu of using daily average concentrations over the exposure period.

- Using the maximum-modeled value anywhere in the study area, including areas not accessible to the public, in lieu of the value where actual receptors (people) may be exposed.

DuPont recommends the District adopt an acceptable risk range and work with daily average exposure values at locations of actual potential for exposure to create a more reasonable and realistic assessment methodology.

In closing, DuPont believes that the District should revert to an input-based decision making process for addressing suspected risk from air contaminant emissions in Jefferson County. This process would incorporate all sources of toxic air pollution, including mobile sources. In addition, DuPont requests that the District give careful consideration to comments regarding methodology for assessing risk from toxic air contaminants, as they apply to scientific research.

PRELIMINARY REGULATORY IMPACT ASSESSMENT COMMENTS

The West Louisville Air Toxics Study Risk Management Plant: Part 1 Process and Framework represents a thoughtful approach to local air quality issues that, regrettably, has not been followed.

The West Jefferson County Community Task Force issued a Risk Management Plan (RMP) in April 2003 that described a thoughtful approach for "identifying, evaluating, selecting and implementing actions to reduce risk to human health". The approach presented in the RMP included a number of constructive elements that appear to have been ignored in the current STAR program. For instance:

- The RMP included the identification of sources of emissions. "The sources of any chemical that exceeds target levels at monitored sites must be identified so proper action can be recommended. The identification process will try to determine the percentage of emissions that are linked to a specific source or combination or sources." The Plan continues to describe the three main categories of sources as point, mobile and area types. This key identification step would help prioritize and target the universe of emission sources in order to examine all possible sources where real risk reductions could be made. Skipping this step is a critical omission that leads to risk management "solutions" that may not solve the real problem by missing one or more of the major source categories altogether.
- The RMP rightly presented efforts to improve air quality as a series of risk management decisions based first on understanding the problem, and then considering options for risk reduction. Factors to be considered in the process included the recognition that existing and planned regulations are already in place that may address some local concerns. The RMP also recognized the need to interpret results of the WLATS based on the uncertainties in the study. Finally, the Plan also saw the importance of considering the costs and benefits associated with risk management decisions.
- The RMP embraced a holistic approach to addressing emission reduction opportunities "in a coordinated and systematic way across the range of sources that may exist for a chemical of concern." Further, it encouraged engaging stakeholders in the process of understanding and addressing emissions reduction opportunities through good faith dialogue and consensus building. Their recognition that implementing risk management strategies "will require a collaborative effort among government agencies, business and industry, and the community at large" showed insight into establishing an open and balanced process that will serve all the stakeholders of the Louisville area.

DuPont would like to further assess the preliminary regulatory impact analysis during an additional 30-60 day public comment period, as requested above.

PROPOSED REGULATION COMMENTS

Regulation 1.02 Definitions

1. The definition of "ambient air" should reflect the areas only to which the general public has access. By defining "ambient air" as proposed, the District has added an unnecessary layer of conservatism, as the modeling methodology proposed in the STAR program is based on 70-year/24-hour continuous exposure. Therefore, the revised definition of "ambient air" is not appropriate. *(Section 1.7)*
2. The last sentence of the definition of "Excess Emissions" should be removed. The definition for "excess emissions" should include only emissions above an applicable emission standard, or otherwise enforceable limit. *(Section 1.30)*

Regulation 1.06 Stationary Source Self Monitoring, Emissions Inventory Development, and Reporting

3. While a change in schedule for enhanced emission inventory data has been revised from Draft 1 to Draft 2 of the regulations, the requirement for retroactive reporting for Category 1 TACs for calendar year 2004 has not been resolved in the proposed regulation. The District should regulate enhanced monitoring requirements only effective for reporting periods following promulgation of the regulations. It is noted that a six month extension for the due date is possible as described in Section 5.2.4; however, the reporting period is still retroactive. *(Section 5.2.1.1)*

4. DuPont suggests that detailed security sensitive information required by Section 5.3 of this regulation be available on site upon request. If the District insists that the data be submitted, DuPont trusts that the companies will be able to confidentially submit any security sensitive information requested including, but not limited to, building plot plans drawn to scale and location of equipment. EPA has recognized the sensitive security nature of this type of information, reflected in restrictions placed on data submitted for risk management plans under Clean Air Act 112r. *(Section 5.3)*

Regulation 1.07 Excess Emissions During Startups, Shutdowns, and Malfunctions

5. Minimizing emissions may be inconsistent with shutting down a process, as a startup/shutdown sequence may result in more emissions than simply working to line out a process or eliminate an operating problem causing excess emissions. Therefore, DuPont requests that the District remove the second sentence of this paragraph. *(Section 1.2)*

6. DuPont requests that the District replace the phrase "received by the District" to "to the District" to further clarify that the requirement is satisfied upon sending an e-mail notification. The facility may have no control over a rejected e-mail that could not pass the APCD's firewall. *(Section 2.6.3)*

7. The immediate notification requirement (within one hour) for unplanned events causing excess emissions should allow the provision that this requirement can be also satisfied with a notification call to 911. This prevents unnecessary duplication during a time when resources are best employed resolving the immediate situation. Simply adding an additional hour to the response time is not sufficient resolution of this issue. Metro agencies should work together to ensure that proper agency notifications are made upon a 911 call. *(Section 3.3, Section 4.1)*

Regulation 1.20 Malfunction Prevention Programs

8. The definition of "affected facility" should be clearly defined so that facilities become subject to this requirement only based on pre-established criteria. A metric or benchmark, such as a number of occurrences for a particular source or control device per time period. DuPont suggests that a reasonable #/time criteria for determining applicability be applied only to excess emissions, defined as suggested in comments above for draft Regulation 1.07. In response to comments, the District did not propose #/time criteria for applicability of this regulation. *(Section 1.1)*

9. Sufficient notice is required for implementation of a malfunction prevention plan. Section 3.1.10 is not sufficient. DuPont suggests 120 days for implementation of the program. *(Section 3.3)*

10. The requirements should be stated in the operating permit as district-only enforceable requirement, only by reference. Referencing the plan will allow ease in maintaining an evergreen document. Regulation 1.20 should not be included in the SIP. *(Section 3.3)*

Regulation 1.21 Enhanced Leak Detection and Repair Programs

11. An enhanced LDAR program should correlate with the federal MACT LDAR standards to the greatest extent possible for consistency in complying with monitoring and reporting requirements. In Regulation 1.21, the leak definitions for various components are lower than SOCMI HON definitions. Lowering the leak definition from 500 ppm (SOCMI HON for light liquid service valves) to 100 ppm (STAR) serves no environmental benefit or increased protection of public health. The important factor is to have a leak monitoring program, not to lower the definition from 500 ppm to 100 ppm. For example, using EPA's guidance document entitled "Protocol for Equipment Leak Emission Estimates" (Publication EPA-453/R-95-017), which provides SOCMI leak rate screening correlations, the difference in emissions for a valve in light liquid service leaking at 500 ppm and 100 ppm is roughly 2-3 pounds a year. At a 0.5% leak rate for a facility monitoring 500 valves, this would equal less than 10 pounds (0.005 tons) of emissions a year. This slight difference in emissions, applicable only to components which were leaking, does not justify the burden of maintaining multiple recordkeeping and reporting systems for the same components. Similarly, for other types of components, lowering these definitions does not contributed to greater protection of public health; however,

implementation leads to significant expenses to businesses subject to this regulation. Streamlining is not a good option as it causes District-specific regulations to be subject to federal enforceability; this causes a competitive disadvantage for facilities operating in Jefferson County. DuPont requests that the regulations reflect the same leak definitions as 40 CFR 63 Subpart H. *(Section 1.4)*

12. The definition of "affected facility" includes sources subject to promulgated MACT standards for which a compliance date is in the future. This definition makes these sources almost immediately (as soon as 120 days) subject to requirements for which the facilities may not have yet made preparation (tagging, training, etc.). The source should be subject to these requirements on the same schedule as the MACT standards. Section 13 was added in Draft 2 of the regulation to include provisions for a schedule; however, DuPont believes the schedule EPA has already put forth for these programs is adequate – CFR Parts 60, 61, and 63. *(Section 1.20)*

13. Repairing a significant leak is a high priority and, although usually possible, a first attempt to repair is not <u>always</u> possible within one business day of detecting a leak (may have to construct scaffolding, employ contractors, empty equipment, write lockout plans or procedures, etc.). For example, necessary contractors may not be immediately available (especially on weekends). The District should either consider extending this requirement to at least three days or put forth a provision for extending this requirement to three days. *(Section 4.1)*

14. Components of the proposed training program are not outlined. The District should clearly state the training requirements as well as records retention for any training documents. It will be difficult to assess compliance with this section, as proposed, since the training elements are not specified. *(Section 6)*

15. Section 12, which requires third party audits, is an unnecessary cost burden for facilities subject to this regulation. Existing LDAR programs include quality assurance/quality control (QA/QC) procedures for monitoring components per EPA Method 21, including, but not limited to calibration of field instruments. A third party audit is yet another expense which will not provide additional protection of public health. *(Section 12)*

16. Per these draft regulations, a leak detection plan is required within 120 days of promulgation of this regulation. This is an onerous requirement that places undue burden on affected sources. The District assumes that the regulated companies have unlimited resources to address manpower-intensive immediate requirements for enhanced emissions inventories, LDAR plans, modeling, etc. The timing to implement all of these requirements simultaneously has not been clearly justified by the District in the regulatory impact analysis. *(Sections 13.2, 14.2)*

17. Applying leak detection and repair requirements to inorganic sources may not be justifiable, and the regulation, as proposed is vague. *(Section 14)*

<u>Regulation 2.08 Emissions Fees, Permit Fees, Permit Renewal Procedures, and Additional Program Fees</u>

18. There should be a clear, transparent plan for funding the extensive STAR regulations. Thus far, the District has not disclosed a plan for funding the STAR program beyond FY2005. During informal public meetings, the District stated that funding for the STAR program for FY2005 would come from three sources - $261,000 from permit fees, $260,000 from an EPA grant, and $174,000 from the VET surplus. What is the plan for making up the difference left when the EPA grant and VET surplus are no longer available? The District should divulge plans for funding the STAR program beyond FY2005. If no plan exists, the District should develop a plan, which should be disclosed and subject to further public review and comment, prior to implementation of the STAR program elements.

19. DuPont is concerned that the fees have the potential to be significant, especially after FY2005, for the small number of Title V sources in Jefferson County if promulgated as proposed. DuPont urges the District to proactively estimate and disclose expected program fees for the next five years, along with company identification and expected fees for each facility based on previously submitted data to the District. Facilities must be able to anticipate significant fees at least a year in advance to facilitate adequate budgeting. Unless the fee increases will be only subject to increases in the Consumer Price Index, DuPont suggests that an annual published fee schedule, which includes estimated increases for five years forward, be required in this regulation. This fee schedule would be made available at least 12 months prior to the due date for the set fee and would be updated and made available annually by the District. Leaving these questions unanswered leads to an uncertain business environment and is counteractive to attracting new business and jobs to Jefferson County. *(Section 6.3)*

20. For substantial fees, payment may have to be made corporately, which could require additional time. A better approach than suspending a facility's permits after 60 days would be to invoke a late payment penalty, such as 2% per month, for payments received after the due date. Additionally, there could be a cut-off period, say six months, in which permit suspension would occur. Clearly state in the regulation that the payment must be postmarked or received by the stated due date to avoid confusion. *(Section 6.4)*

Regulation 5.20 Methodology for Determining Benchmark Ambient Concentration of a Toxic Air Contaminant

21. The unit risk estimate (URE) available for chloroform in the IRIS database is a 1987 value that does not include information from all available studies and is being re-evaluated by EPA. A more recently reviewed value (1990) that includes more study information is available through the California Office of Environmental Health Hazard Assessment (OEHHA) Air Toxics Hot Spots program. The California EPA URE "represents the best estimate using a nonthreshold linear procedure and using most of the data on the carcinogenicity of chloroform. It included analysis by PBPK modeling of metabolized dose, as well as analysis of potency based on applied dose" (1999 Technical Support Document for Describing Available Cancer Potency

Factors, available at http://www.oehha.org/pdf/HSCA2.pdf). The impact of using the outdated IRIS value in lieu of, for instance, the California URE value is an overstatement of risk by 400 percent (factor of 4).

22. US EPA's Risk Characterization Handbook (US EPA, 2000) defines four qualities of an effective risk characterization as transparency, clarity, consistency and reasonableness. Effective regulations that incorporate risk assessment as a component should possess these same qualities. The Proposed Regulations Sections 5.20, 5.21 and 5.22, in their present form, are deficient in all four categories. Specific examples of these deficiencies and recommended changes are provided below.

23. Section 1 grants unduly broad discretion to the District to make determinations on risk for which required skills and experience in toxicology and risk assessment are required. A scientifically sound methodology for making such determinations should be developed through a consensus approach with the regulated community and recognized scientific experts and be a part of any final regulation. *(Section 1)*

24. The hierarchy for determining whether a compound is a carcinogen (as addressed in Section 2) is flawed by excluding other agencies such as the US EPA and California OEHHA . DuPont believes that the hierarchy should be: (1) IRIS, (2) NTP, (3) IARC, and (4) OEHHA. These agencies and organizations have specific regulatory mandates, personnel and expertise to classify substances for potential human carcinogenicity. Section 3.3 should be changed to reflect this hierarchy as well. *(Section 2.1, Section 3.3)*

25. Without the technical expertise to understand and apply these guidelines, these sections will be subjective and arbitrary, and should be removed. *(Sections 2.1.4-2.1.4.2.3)*

26. This discussion is vague and creates additional uncertainty in the regulated community. We believe the basis for determination of carcinogenicity must be the hierarchy proposed in Comment 3. Before the District could decide to classify for itself based on section 2.1.4, numerous supplemental criteria must be addressed to ensure that high quality studies are used in the assessment. *(Section 2.2-2.2.2)*

For example, data to be used as the basis for BAC_C development should meet the following minimal essential criteria:

- Inhalation studies should be used preferentially as the basis; cancer studies by other routes of exposure should not be used unless clear evidence exists that portal of entry (i.e. respiratory tract) effects do not occur or that the lung is critical to the metabolic disposition and toxicological properties of the substance.

- Studies should be well documented (ideally conducted by good laboratory practices) using established protocols, have adequate description of historical control responses and be published in peer-reviewed scientific literature.
- Where human epidemiology data exists and conflicts with animal data, modifications to the URE should be permissible, using human data preferentially.
- Where sufficient mechanistic data exists to show that a deviation from linear dose response exists, application of threshold-based, non-linear risk assessment approaches (Margin of exposure approach) should be acceptable.
- The newest toxicological data should be used for URE evaluation. URE based on obsolete data or risk assessment approaches should be reassessed with the newest data.

27. The basis for the universal use of 10^{-6} risk is inconsistent with EPA's methodology, and no scientific justification for the higher level of stringency has been established. The District's proposal is unduly stringent, applied only to fixed facilities, and arbitrary and capricious. It should be changed to be consistent with the USEPA methodology described below. *(Section 3.1)*

28. A $1x10^{-6}$ risk is typically used for "screening purposes" as a target risk level. However, with respect to making risk management decisions, a range of target risks $1x10^{-4}$ to $1x10^{-6}$ is typically used, based upon past regulatory experience (Travis and Hattemer-Frey, 1988). For example, in response to the 1987 vinyl chloride Section 112 Clean Air Act decision (NRDC, 1987), USEPA decided it would base its regulatory decision on quantitative risk assessment using the general policy that the lifetime added cancer risk for the most exposed person of 1 in 10,000 (1×10^{-4}) might constitute acceptable risk and that the margin of safety required by statute and reinforced by the court should reduce the risk for greatest number of persons to an individual added lifetime risk of no more than one in one million (1×10^{-6}). US EPA has repeatedly rejected the opinion that it can establish a universal (*i.e*., brightline) acceptable risk that should never be exceeded under any circumstances, and that guidance provided under one statute may have little relevance to others because of program goals and objectives. It is difficult to conceive how the District Air Board proposes to improve on the scientific state of the knowledge. *(Section 3.1)*

29. The proposed regulation lists a hierarchy of three regulatory agencies (US EPA, OEHHA and Michigan), as references for BAC_C development. A single methodology is desirable to avoid confusion and to ensure consistency. We recommend that the method used for IRIS is preferable among the three approaches. Several secondary approaches (some no longer current) are referenced should no BAC_C exist from any of the three agencies. A primary problem with this hierarchical approach is that these agencies may apply different criteria, rely on different critical studies, apply different dose response models, and use different points of departure in their risk characterization. Consequently, three different URE may be identified by the three agencies (See comments for 3.3.2 and 3.3.3). This is problematic since

specific criteria are not included that would identify a single URE in case multiple URE existed. *(Section 3.3)*

When multiple values are available for a chemical, the lowest value should not be selected as a matter of default for the sake of conservatism. In addition, use of a composite value (mean or geometric mean of several possible BAC values) is not recommended. Rather, several factors should be considered, including (1) date of the assessment; (2) appropriateness and consistency of the methods used; and (3) critical assumptions made.

The potential availability of different URE values from the different agencies could be eliminated if a single agency and its approach were used exclusively. Given the broad list of substances already evaluated and its established protocol, the US EPA IRIS approach described in chapter 12 of the FERA Air Toxics Risk Assessment Reference Library Technical Resource Manual should be used for all URE determinations.

30. The date of the IRIS assessment must be considered when selecting an appropriate URE or RfC value (see parts 3.3.1.& 4.1). While US EPA's IRIS database is often cited as the first-tier source for chronic toxicity values for human health risk assessment, the information it contains is not always current. Additionally, if US EPA's current methods for cancer and non-cancer dose-response assessment (US EPA, 1999; 2002; 2003; 2004) are adopted as the "standard" for risk assessment, then up-to-date values derived by these methods should be adopted over values derived by other methods. It will again be important that the District develop and maintain the personnel to develop scientifically justifiable values consistent with the latest EPA approach. *(Section 3.3.1)*

31. The CA and MI lists should be removed from the hierarchy used to determine URE. Methods used by the California Office of Environmental Health Hazard Assessment (OEHHA) and the Michigan Department of Environmental Quality (DEQ) differ from current USEPA methods, and in many ways resemble USEPA methods as they were prior to method changes in 1992 and 1996. For example, both California and Michigan use an allometric scaling factor of 0.67 compared to a value of 0.75 (US EPA, 1992) to extrapolate equivalent doses from animal studies to humans. This difference alone can result in URE values that are more than 50% and 85% larger than is supported when based upon rat and mouse studies, respectively. Another important difference is that both OEHHA and DEQ estimate the slope of cancer dose-response relationship using the upper 95% confidence limit in the linear term (q1* value) as predicted by the linearized multistage model. Under current USEPA guidelines (USEPA, 1996; 1999; 2003), the q1* is no longer used, but instead the slope is estimating by linear extrapolation from a point of departure [*e.g.*, the dose corresponding to a 10% increase in extra risk (ED10) and its lower confidence limit (LED10)]. Reliance upon the q1* can significantly overestimate the cancer slope factor since the lower bound (on dose) fit of linearized multistage model has a

tendency to predict supralinear curves, even in cases when there is no information to suggest that the dose-response relationship is truly supralinear. The extent to which the q1* overestimates the cancer slope factor will vary from chemical to chemical. Finally, both California and Michigan adjust their cancer potency estimates by a factor of (animal exposure duration/animal life expectancy)^3 when less-than-lifetime animal studies are used as the basis. This approach is not practiced by USEPA (1996, 1999, 2003). For example, when a one-year rodent study serves as the basis of cancer potency, this adjustment would increase the URE value by a factor of 8 without a consideration of the underlying mode of action. For these reasons and to avoid confusion and inconsistencies in BAC_C values, we believe that OEHHA (section 3.3.2) and DEC (sections 3.3.3 and 3.3.4.4) values should be removed from the hierarchical approach used for URE. *(Sections 3.3.2 and 3.3.3)*

32. The scientific basis for the default value of 0.0004 ug/m^3 is not transparent or specified. In the absence of animal bioassay data, the cancer potency equivalent to this default is highly questionable. Application of a default value without scientific justification misleads the public about actual risk. Thus, utilization of this value would be arbitrary and capricious. If a BAC_C cannot be established from existing scientific data, then the District should not assess carcinogenic risk. *(Section 3.3.5)*

33. There is no logical connection between the underlying source of the BAC value and the method for estimating the maximum ambient concentration from emission rates. A specification is made for use of "average time period." It is unclear from the proposed rule precisely to what this term is referring or what role it is expected to play. All of the benchmark ambient concentration (BAC) methods in these sections, regardless of whether the underlying basis is an unit risk estimate (URE), reference concentration (RfC), reference dose (RfD), occupational exposure limit (OEL), or acute toxicity value, adjust for differences in exposure time, frequency, and duration, and therefore, the resulting BAC values are protective for lifetime, continuous exposures. *(Section 3.4)*

34. There is no justification provided for use of an annual averaging time for cancer. This might mask effects attributable to peak exposures. *(Section 3.4)*

35. Several methods are specified. Some of these methods are unjustifiable scientifically and contradict risk characterization guidance given by EPA for non-cancer endpoints. This District would be better served by implementing a single approach based on repeated dose animal studies (e.g., chapter 12 of the FERA Air Toxics Risk Assessment Reference Library Technical Resource Manual), minimally of 4 weeks duration. To this end, sections 4.2 and greater should be deleted. In addition, DuPont offers the following specific comments:

36. As described in comments for BAC_C for section 2.2, data to be used as the basis for BAC_{NC} determinations are not adequately defined. Data should meet the following minimum essential criteria:

- Studies should use inhalation as the route of exposure.
- Studies should be based on durations of either 4 or 13 weeks of duration. Shorter duration exposures are less reliable and impose additional uncertainty factors to extrapolate short term-effects to chronic-effects.
- Endpoints cited should be based on toxicologically adverse effects; statistically significant effects need to be interpreted opposite biological significance.
- Studies should be well documented, conducted by good laboratory practices using established protocols, and be published in peer-reviewed scientific literature.

37. The application of different methodologies, such as California's REL, would likely jeopardize the consistency of the BAC values derived from the EPA methodology. California's methods for deriving recommended exposure limit (REL) values may differ from USEPA's methods for deriving RfC values. For example, these two agencies may apply different uncertainty factor values, particularly for database deficiencies, to the same no-observed-adverse-effect-level (NOAEL) value, such that the resulting safe concentration values differ by as much as a factor of 10. *(Section 4.2)*

38. This section is inappropriate and should be removed. Oral or dermal data should not be used to determine BAC_{NC} where inhalation is the primary route of exposure. As noted in 4.12, oral to inhalation extrapolation should only be done where previous data exists to show that oral to inhalation BAC_{NC} determination can be justified. Although the method presented represents the default approach used by US EPA and other agencies for a number of years, it requires a careful consideration of two important factors that can complicate this extrapolation: (1) it should be determined if the effect of interest is a systemic effect or a point-of-contact (i.e., nasal or respiratory tract) effect. While extrapolation of the former may be appropriate, extrapolation of the latter is not advised; and (2) it should be determined if there is a "first-pass" metabolism effect in the liver or the lung. If either is expected, more sophisticated methods for extrapolation, such as physiologically based pharmacokinetic (PBPK) modeling may be required. *(Section 4.3)*

39. Although default values of 70 kg and 20 m^3/day have been used in the past for the purposed of extrapolating toxicity criteria across routes of exposure, they are not supported by the best available data. US EPA's exposure factors handbook (US EPA, 1999) recommends values of 71.8 kg (average for adult men and women) and 13.3 m^3/day (average of 11.3 and 15.2 m^3/day). Continued use of the unsupported default values results in BAC_{NC} values that are conservative by more than 50%. This section should be changed to be consistent with the EPA values. *(Section 4.3)*

40. These sections should be removed for reasons repeatedly stated throughout these comments. *(Section 4.4-4.11)*

41. It is inappropriate to use OSHA or TLV occupational exposure limits as the basis for the community BAC_{NC}. The OSHA and TLV are intended to protect workers from adverse health effects; this is interpreted to encompass all adverse health effects, including cancer. Thus, the definition of BAC_{NC} becomes confused when the OEL is based on cancer and non-cancer endpoints. *(Section 4.5)*

Additionally, the need to adjust OEL values for differences in exposure duration and time needs also to take into account the mode of action by which the adverse effect is produced. For endpoints that are attributable to peak concentrations, such as respiratory irritation, this adjustment may not be necessary and would result in BAC_{NC} values that are unnecessarily restrictive by a factor of up to 100.

Collectively, these issues again suggest that a single approach, recommended in our general comments on Section 4 should be used for BAC_{NC}.

42. The use of multiple uncertainty factors described in this section by incorporating results from short-term studies renders the derived BAC_{NC} value meaningless since the composite uncertainty is so large, it is of questionable value. *(Section 4.6)*

43. The justification for use of short-term or acute studies in setting BAC values is not documented, and is not supported by US EPA and other authoritative bodies. *(Sections 4.6-4.10)*

Although approaches on the use of short-term or acute toxicity data in human health risk assessments for chronic exposures have been published in the past (Venman and Flaga, 1985; Layton et al., 1987), their application in a regulatory setting is neither prudent nor reasonable for current risk assessment practices. The net uncertainty factors in these sections of the proposed rule range from 3,500 deriving RfD and RfC values (USEPA, 2002) and by OEHHA (to 2,000,000 far exceed the maximum value of 3,000 adopted by USEPA for OEHHA, 2000). Such large values do not appear to recognize the considerable overlap between the various adjustments and uncertainty factors, and as such are expected to result in BAC values that are unnecessarily restrictive and unrealistic.

Emphasis should be placed on using high quality chronic and sub-chronic rather than using the results of studies that use a 7-day (an atypical duration since most studies are 2, 4 or 13-wk duration) or shorter exposure duration. Chemicals that lack even a single sub-chronic or chronic toxicity studies do not meet the minimum database requirements for conducting a human health risk assessment for human health (USEPA, 2002).

44. As noted above, there is no scientifically justifiable basis for determining inhalation BAC_{NC} based on acute lethality data. There is no established relationship between lethality and what might prove to be selective effects on organ systems (e.g.,

reproductive function) resulting from cumulative, low level exposure. The introduction of such large uncertainty (with factors totaling up to 2,000,000) yields essentially meaningless BAC_{NC} values. For this reason, in cases where repeated inhalation data do not exist, a BAC_{NC} should not be determined. *(Sections 4.8-4.11)*

45. The basis for the default value of 0.04 ug/m^3 is not transparent or specified, and thus is arbitrary and capricious. In the absence of animal bioassay date, the non-cancer BAC equivalent to this default misleads the public about actual risk. If a BAC_C cannot be established from existing repeated exposure animal bioassay data, then non-carcinogenic risks should not be assessed. *(Section 4.11)*

46. Here and elsewhere in section 4, a specification is made for use of "average time period." It is unclear from the proposed rule precisely to what this term is referring or what role it is expected to play. All of the benchmark ambient concentration (BAC) methods in these sections, regardless of whether the underlying basis is an unit risk estimate (URE), reference concentration (RfC), reference dose (RfD), occupational exposure limit (OEL), or acute toxicity value, adjust for differences in exposure time, frequency, and duration, and therefore, the resulting BAC values are protective for lifetime, continuous exposures. *(Section 4.12)*

However, in some cases an annual average time other cases a 24-hour average time is recommended (BAC source = RfC, REL, RfD) or an 8-hour average time is recommended (BAC source = OEL). is recommended (BAC source = URE, short-term, or acute toxicity value), while in The "average time" may be related to Table 1 of Section 2.2 for Proposed Regulation 5.22. However, since BAC values are protective of lifetime, continuous exposures, there does not appear to be a logical connection between the underlying source of the BAC value and the method for estimating the maximum ambient concentration from emission rates. Some additional explanation, clarification, and revision of the methods is required regarding the use of the term "average time period."

47. This section should be removed. If methodologies as recommended above do not developed a BAC_{NC}, the District does not have the capability of making this scientific determination. *(Section 5)*

Regulation 5.21 Environmental Acceptability for Toxic Air Contaminants

48. : The terms "goal" and "standard" are undefined, making this section vague. By introducing a Board review and public comment in application of the goal" the District has applied the goals as a standard. Allowing such subjectivity and non-scientific input to the process leads to uncertainty in the regulated community, resulting in an unfavorable business environment. *(Section 1)*

49. The four-tier structure is unnecessarily broad and overreaching, adds 188 chemicals not identified as significant risks, and is therefore an arbitrary and capricious addition to these regulations. It should be simplified - see comments on 5.23. *(Section 1.51-1.53)*

50. The environmental acceptable level for a carcinogen (EALc) values specified in the table range from 1.0 to 3.8. Although the value of 1.0 is recognized as corresponding to a default *de minimis* risk of $1x10^{-6}$, it is unclear precisely how the value of 3.8 (corresponding to a risk level of $3.8x10^{-6}$) was determined as a "goal." Some additional explanation and derivation of this goal is required. More importantly, there should be some additional language introduced here regarding the range of acceptable risk (*i.e.,* $1x10^{-6} – 1x10^{-4}$, see comment on Proposed Regulation 5.20, Section 3.1), which would indicate that EALc values of up to 100 may be considered acceptable. *(Section 2.2)*

51. By summing EAL values across toxic air contaminants (TACs), a hidden conservatism is introduced by summing upper-bound estimates of risk. Summing the central tendency estimates of risk across TACs provides a more appropriate estimate of the combined risk. *(Section 2.2)*

52. The environmental acceptable level for non-carcinogens (EALnc) values specified in the table ranges from 0.2 to 0.38. These values are less than the target hazard quotient (HQ) of 1.0 typically used in non-cancer risk assessment, and it is unclear how these values were determined as a "goals". Additional explanation and justification of these goals is required. A margin-of-safety approach (*i.e.*, evaluation of the ratio of the NOAEL or LOAEL to the maximum exposure concentration) should be given consideration as a replacement for the HQ approach used for non-cancer endpoints. *(Section 2.2)*

53. The EALc values specified in the table range from 1.0 to 7.5. Although the value of 1.0 is recognized as corresponding to a default *de minimis* risk of $1x10^{-6}$, it is unclear precisely how the value of 7.5 (corresponding to a risk level of $7.5x10^{-6}$) was determined as a "standard." Some additional explanation and derivation of this standard is required. More importantly, there should be some additional language introduced here regarding the range of acceptable risk (*i.e.,* $1x10^{-6} – 1x10^{-4}$, see comment on Proposed Regulation 5.20, Section 3.1), which would indicate that EALc values of up to 100 may be considered acceptable. *(Section 2.5)*

54. By summing EAL values across TACs, a hidden conservatism is introduced by summing upper-bound estimates of risk. Consideration should be given to summing the central tendency estimates of risk across TACs to provide a more appropriate estimate of the combined risk. *(Section 2.5)*

55. The EAL_{NC} values specified in the table ranges from 0.2 to 0.75. These values are less than the target HQ of 1.0 typically used in non-cancer risk assessment, and it is

unclear precisely how these values were determined as a "goals" and "standards." Some additional explanation and derivation of these values is required. A margin-of-safety approach (*i.e.,* evaluation of the ratio of the NOAEL or LOAEL to the maximum exposure concentration) should be given consideration as a replacement for the HQ approach used for non-cancer endpoints. *(Section 2.5)*

56. It is unclear how the value of 10 (corresponding to a risk level of $1.0x10^{-5}$) was determined as a "goal." Additional explanation and justification of this goal is required. More importantly, there should be some additional language introduced here regarding the range of acceptable risk (*i.e.,* $1x10^{-6} – 1x10^{-4}$, see comment on Proposed Regulation 5.20, Section 3.1), which would indicate that EALc values of up to 100 may be considered acceptable. *(Section 2.8)*

57. By summing EAL values across TACs, a hidden conservatism is introduced by summing upper-bound estimates of risk. Consideration should be given to summing the central tendency estimates of risk across TACs to provide a more appropriate estimate of the combined risk. *(Section 2.8)*

A margin-of-safety approach (*i.e.,* evaluation of the ratio of the NOAEL or LOAEL to the maximum exposure concentration) should be given consideration as a replacement for the HQ approach used for non-cancer endpoints.

58. This section deals with additivity of response that could affect the EAL. There is comparatively little data to justify quantitative adjustments for EAL on cancer or noncancer effects. At a minimum, there should be very clear guidance on what constitutes the minimal core data needed that could imply a relationship for additive effects. This guidance must consider whether the mechanism of action is comparable and whether the same target organs are involved. Conversely, if guidance on additive effects are included in a revised procedure, then the procedure should allow adjustments in the opposite direction if the scientific data could support antagonistic interactions of different substances. *(Section 4.10)*

Regulation 5.22 Procedures for Determining the Maximum Ambient Concentration of a Toxic Air Contaminant

59. As indicated in comment to Proposed Regulation 5.20, Section 3 through 4, the term "averaging time" is not transparent, and its application here may not be appropriate. All of the BAC values derived by the methods described in proposed regulation have been adjusted for differences in exposure time, frequency, and duration. Therefore, these values are protective of lifetime, continuous exposures. As such, it is only appropriate to compare these values to a reasonable, upper-bound look at some more average concentration encountered during chronic or lifetime exposures. The factors listed in Tables 1 and 2 are not documented along with any underlying assumptions. Therefore, it is not possible to determine if their application to the corresponding

emission rates will result in concentrations at the point of exposure that are appropriate for a chronic duration.

As indicated in comment to Proposed Regulation 5.20, Section 3 through 4, the term "averaging time" is not transparent, and its application here may not be appropriate. All of the BAC values derived by the methods described in proposed regulation have been adjusted for differences in exposure time, frequency, and duration. Therefore, these values are protective of lifetime, continuous exposures. As such, these values should only be compared to an appropriate average concentration (*e.g.*, arithmetic mean and 95% upper confidence limit) that might be encountered during chronic or lifetime exposures. The factors listed in Tables 1 and 2 are not documented along with any underlying assumptions. Therefore, it is not possible to determine if their application to the corresponding emission rates will result in concentrations at the point of exposure that are appropriate for a chronic duration. *(Sections 2.2 & 3.8)*

Regulation 5.23 Categories of Toxic Air Contaminants

60. Good science should lead the way to understanding realistic air quality levels and associated health concerns. When risk is overstated due to an overly conservative interpretation of data and outdated science, real risk concerns cannot be identified and targeted for improvement.

Concerns over air quality in the Louisville area are based largely on results of calculated risk published in the West Louisville Air Toxics Study (WLATS). Review of the WLATS suggests it is considerably overstating risk/hazard levels in the Louisville area due to its handling of the uncertainty contained in the monitoring data and the methodology used to calculate risk values.

- A large inventory of ambient air data was collected for the WLATS between April 2000 and April 2001 for assessing concentrations of air toxics in the Louisville area. However, the vast majority of the data are "qualified" data that were either (1) estimated because they were outside the normal expected range of precision or (2) assumed to be half of the detection limit because the value was a "non-detect". The impact of relying on qualified data to generate risk calculations can be significant. For example, chloroform was assessed as a Category 1, high priority chemical. However, the basis for that conclusion rests on 247 data points of which 56% were non-detected values that were assumed to be present at ½ the method detection limit. In addition, 28% of the data were estimated (J values) because they were below the expected range of precision. In fact only 16% of the monitoring data for chloroform were quantified above the detection limit and contained no qualifiers. Reliance on qualified data creates considerable uncertainty about actual ambient air concentrations. This uncertainty carries through to risk calculations and to the assessment of acceptable air quality in Louisville.

- Outdated statistical methods were used that likely led to an overestimate of average ambient air concentrations. The 95% upper confidence limit (UCL) of the mean is typically used in risk calculations to provide a conservative estimate of the true average concentration at a location. When the data follow a certain pattern (i.e., are distributed lognormally), a number of methods are available to estimate the 95% UCL. The H-statistic method used in the WLATS was recommended by EPA in 1992 guidance documents, but has since been shown to overestimate the UCL of the mean as compared with other available methods, such as the bootstrap and the jackknife methods. This fact was documented as a Technology Support Center Issue by EPA's Office of Research and Development in a 1997 document entitled "The Lognormal Distribution in Environmental Applications" (EPA/600/R-97/006). The over-estimation of ambient air concentrations carries through to risk calculations and to the assessment of air quality in Louisville.

The above methods combine to create an overstatement of risk for each compound at each location, and have the cumulative effect of overstating air toxics issues for the Louisville area. Further, these overly conservative risk estimates were used to create a Category 1 list of prioritized compounds that may or may not be contributing to risk above the 1×10^{-6} level in the area. The practice of adding layers of conservatism and relying on outdated science leads to an unrealistic assessment of air quality. *(Section 1.2)*

61. DuPont believes it appropriate to address all sources of TAC emissions from Category 1 chemicals prior to imposing further requirements on industrial sources of Categories 2, 3, and 4 chemicals. See comments above in the Executive Summary. *(Sections 2.2, 3.2, 4.2)*

62. The District has somewhat stated its intent in public meetings with regard to treatment of metals and metal compounds, especially Cr^{3+} vs. Cr^{6+}, but that has not been stated in the proposed regulations. Also, the District has not given guidance in the regulations for compounds which may fall into more than one category.

63. DuPont support's AIK's comments regarding the appropriate use of EPA's Relative Risk Screening analysis for determination of the need to impose environmental acceptability evaluations on existing sources which emit a Category 2 chemical. *(Section 2)*

Regulation 5.30 Report and Plan of Action for Identified Source Sectors

64. DuPont believes it inappropriate to impose highly-restrictive, and in some cases, unobtainable requirements on industrial sources while delaying implementation of other measures that would have a much more significant impact on air quality. See comments above in the Executive Summary. DuPont suggests that the District focus on assessing necessary measures to improve current air quality and prevent any further harm to the environment, from all sources.